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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,682	08/18/2008	Yukimitsu Suda	TOS-170-USA-PCT	2820

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TOWNSEND & BANTA
601 Pennsylvania Avenue N.W.
Suite 900, South Building
Washington, DC 20004

EXAMINER

JONES JR., ROBERT STOCKTON

ART UNIT	PAPER NUMBER
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1762

MAIL DATE	DELIVERY MODE
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03/22/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/593,682	Applicant(s) SUDA ET AL.	
	Examiner ROBERT JONES	Art Unit 1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

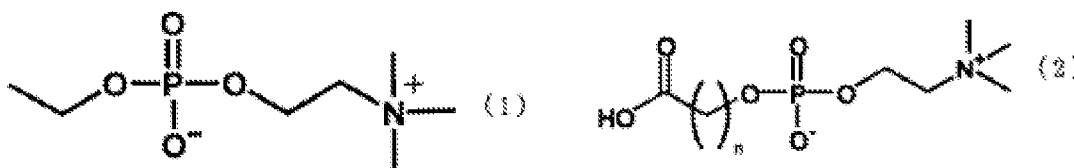
Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claims 1-6 require that a compound of formula (1) is covalently bonded to the surface of a hydroxyl-functional eye lens material through ester bonding of a compound of formula (2):



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However, it is not possible for a compound of formula (1) to be covalently bound in this way. Formula (1) lacks the repeating methylene unit(s) present in (2), and contains no residue of the carboxylic acid group or an ester group which must necessarily be present if (2) is reacted with a hydroxyl-functional surface material. Therefore, it is unclear whether an ester-bound product is formed through the claimed method as expected, or if some variant of (1) lacking the methylene groups and carboxylate residue of (2) is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

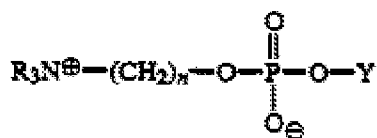
6. Claims 3-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Bowers et al (US 5,422,402).

7. Regarding Claims 3 and 5, the claimed eye lens materials are defined by a product-by-process limitation. It is noted that “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process”, *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966

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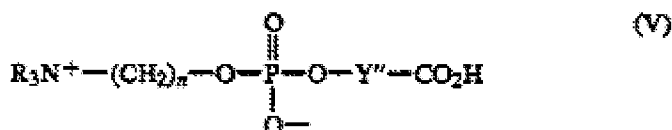
(Fed. Cir. 1985) . Further, "although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product", *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir.1983). See MPEP 2113.

8. Bowers teaches a process for treating synthetic polymers to improve their ocular, hemo, and biocompatibility. Said polymers are widely employed in hard, soft, and intraocular lenses (col. 1, lines 6-12). Bowers' process comprises the steps of (a) where appropriate, activating the surface to be treated; and (b) treating the surface with a compound of general formula (I) (col. 1, lines 29-40):



Step (a) may be omitted where the polymer surface has sufficient free hydroxyl groups for reaction with compounds of formula (I) (col. 4, lines 43-46).

9. Suitable compounds according to formula (I) include carboxylic acid derivatives of phosphorylcholine (col. 9, lines 19-30):



10. Y'' is a group such as $-(\text{CH}_2)_p-$, wherein p is preferably 1-6 (col. 9, lines 28-30; col. 1, lines 52-53). Thus, Bowers discloses a process which results in a contact lens material having hydroxyl groups which have been functionalized by a compound identical to the claimed formula (2) wherein n=1-6.

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11. Absent evidence of criticality regarding the presently claimed process, Bowers' materials clearly meet the requirements of present claims 3 and 5.

12. Regarding Claims 4 and 6, Bowers' process results in reduced protein deposition (col. 1, lines 26-28; table at col. 18). Therefore, the process described above reads on Claims 4-6.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bowers in view of Matsuda et al (US 6,075,066).

17. Regarding Claim 1, Bowers remains as described at paragraphs 8-10 above. Bowers' treatment process is preferably conducted in aqueous medium using a sodium bicarbonate buffer (col. 5, lines 33-38). Thus, Bowers does not teach that the claimed method is carried out in an organic solvent.

18. In the same field of endeavor, Matsuda teaches the formation of contact lenses (Abstract). Matsuda's method involves formation of an ester bond. The ester bonding reaction can be effected by allowing a carboxylic acid derivative to react with a hydroxyl group either in an organic solvent such as DMF, DMSO, HMPA, or THF; or in an aqueous solvent or buffer solution (col. 4, lines 33-51). Thus, Matsuda discloses that when forming contact lens materials, esterification reactions are equally successful when carried out in aqueous or organic solvents.

19. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Bowers in view of Matsuda to substitute an organic solvent for an aqueous solution, as these conditions are taught by Matsuda as being equivalents suitable for carrying out esterification reactions with contact lens materials.

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20. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bowers in view of Matsuda as applied to claim 1 above, and further in view of Valint, Jr et al (US 6,213,604).

21. Regarding Claim 2, Bowers in view of Matsuda remains as applied to Claim 1 above. Bowers teaches that for synthetic polymers which do not have adequate free surface hydroxyl groups, it is necessary to activate the surface before treatment with the compounds of formula (I) (col. 4, lines 55-60). Bowers does not teach a specific method for achieving hydroxylation of a polymer surface.

22. In the same field of endeavor, Valint teaches a method for the surface treatment of silicone hydrogel contact lenses. In one embodiment, the surface of a lens is coated by subjecting said surface to: a plasma oxidation reaction, followed by a plasma polymerization reaction in the presence of a diolefin. Finally, the resulting carbon layer is rendered hydrophilic by a further plasma oxidation reaction (Abstract). In addition to rendering the surface hydrophilic, Valint's process results in a coating which is resistant to delamination and/or cracking (col. 3, lines 66-67).

23. It would have been obvious to modify Bowers in view of Matsuda as applied above, and further in view of Valint to introduce hydroxyl groups as per Bowers' step (a) through plasma treatment as taught by Valiant. This method is demonstrated as being successful in treatment of contact lens materials, and results in resistance to delamination and cracking.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT JONES whose telephone number is (571)270-7733. The examiner can normally be reached on Monday - Thursday, 9 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on 571-272-1114. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RSJ

/David Wu/
Supervisory Patent Examiner, Art Unit 1796